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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,197	02/01/2002	Lan Bo Chen	00530-097001/ 731.02	9895

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EXAMINER
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BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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01/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/062,197

**Applicant(s)**

CHEN ET AL.

**Examiner**

Michael Borin

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 8-16 and 20-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 17-19 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/2007 has been entered.

### ***Status of Claims***

Claims 1-29 are pending. There are no amendments to the claims. Claims 8-16,20-28 remain withdrawn from further consideration. Claims 1-7,17-19,29 are under consideration.

It is noted that art rejections of record are being withdrawn at this time, but will be re-introduced when the new matter (addressed below) is removed from the claim language.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7,17-19,29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 introduces new matter as it addresses acquiring images at different magnifications, low and high, for the first and second fluorophore, respectively. Specification, while addressing using low magnification to identify sources of photons (which is a preceding method step) does not disclose using different magnifications, low for the first fluorophore, and high for the second fluorophore.

The issue is whether acquiring the first image at LOW (emphasis added) magnification constitutes new matter. Examiner maintains the position that acquiring the first image at LOW (emphasis added) magnification constitutes new matter. The specification, p. 9, line 2, is silent about whether the magnification is high or low. Examiner disagrees with applicant's assertion that "it is conventional that, when describing a sequence, one skilled in the art specifies the magnification only at the beginning and does not repeat it unless a different magnification is used". The arguments of counsel can not take the place of evidence in the record., and the cited statement is unsubstantiated. Examiner maintains that , for one skilled in the art it would seem counterproductive to acquire images of two fluorophores at different, low and

high, modifications and thus both to loose resolution of the first image, and to compromise the validity of comparing images acquired at different magnifications. It is noted that applicant further argues that low magnification allows quick scan of events (although no events are addressed in the claims), and high magnification allows to observe each event in detail (p. 11, last paragraph). This is exactly the Examiner's point, that specification addresses using low magnification to register location of photon sources - which is a preceding method step, corresponding to what applicant addresses as "quick scan of events" – and does not address acquiring and recording an image – which corresponds to what applicant addresses as "to observe each event in detail" - namely the first image, at low magnification as now claimed .

In addition, with respect to the applicant's reference to "sequence" of steps in the cited statement, the claims do not stipulate any particular steps, but are rather directed to a method comprising certain steps.

#### Response to arguments

Applicant submits that even if the magnification at which this step is conducted is not explicitly described in the specification, adequate description requirement is met because simple logic dictates that a condition is maintained until a different condition is specified. See p. 10 of response. Examiner responds that the lack of proper description of magnification in the specification can be equally explained by omission of the detail about magnification in describing conditions of acquiring the first image on p. 9, top.

In attempt to resolve the ambiguity, Examiner looked at the working examples. p. 31 describes two experiments on double-labeled tumor cells. In one (first paragraph) cells stained with anti-GD2 antibody and anti-cytokeratin antiserum are BOTH (emphasis added) clearly imaged at the same magnification. In the second experiment, described in the second paragraph (see last lines) fluorescence of BOTH (emphasis added) intracellular cytokeratin labeling and the surface staining of Ep-CAM was imaged at higher magnification. Therefore, neither of the experiments support acquiring first image at magnification lower than the second image as now claimed.

Turning to section of specification cited by applicant, Examiner reviewed page 25, lines 15-18; page 26, lines 20-22; and page 29, lines 12-16, cited in response, p. 10, bottom. However, neither of these sections was deemed as providing support for the claim language at issue.

Thus, Examiner maintains the position that acquiring the first image at LOW (emphasis added) magnification constitutes new matter.

This is an RCE of applicant's earlier Application No. 10/062197. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.  
Primary Examiner  
Art Unit 1631

mlb  
12/28/2007